

# Protocol

## Subtalar Arthroereisis

(701104)

Medical Benefit	Effective Date: 10/01/08	Next Review Date: 01/15
Preauthorization	No	Review Dates: 07/07, 07/08, 09/09, 03/10, 01/11, 01/12, 01/13, 01/14

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary; supporting documentation must be submitted to Utilization Management.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### Description

Arthroereisis (also referred to as arthroisis) is the limitation of movement across a joint. Subtalar arthroereisis or extraosseous talotarsal stabilization (EOTTS) is designed to correct excessive talar displacement and calcaneal eversion by reducing pronation across the subtalar joint. It is performed by placing an implant in the sinus tarsi, which is a canal located between the talus and the calcaneus.

### Background

Flexible flatfoot is a common disorder, anatomically described as excessive pronation during weight bearing due to anterior and medial displacement of the talus. It may be congenital in nature or it may be acquired in adulthood due to posterior tibial tendon dysfunction, which in turn may be caused by trauma, overuse, inflammatory disorders, and other factors. Symptoms include dull, aching and throbbing, cramping pain, which in children may be described as growing pains. Additional symptoms include refusal to participate in athletics or walking long distances. Conservative treatments include orthotics or shoe modifications. Surgical approaches for painful flatfoot deformities include tendon transfers, osteotomy, and arthrodesis. Arthroereisis with a variety of implant designs has also been investigated.

Subtalar arthroereisis has been performed for more than 50 years, with a variety of implant designs and compositions. The Maxwell-Brancheau Arthroereisis (MBA) implant is the most frequently reported, although other devices such as the HyProCure, STA peg and Kalix are also described in the medical literature. The MBA implant is described as reversible and easy to insert, with the additional advantage that it does not require bone cement. In children, insertion of the MBA implant may be offered as a standalone procedure, although children and adults often require adjunctive surgical procedures on bone and soft tissue to correct additional deformities.

### Regulatory Status

A number of implants have received marketing clearance through the U.S. Food and Drug Administration's (FDA) 510(k) pathway. For example, the HyProCure® Subtalar Implant System/Extra Osseous Fixation Device (GraMedica) received marketing clearance in 2004 (K042030), the SubFix™ arthroereisis implant (Memometal Technologies, Bruz, France) received FDA marketing clearance in 2010 (K093820) and the Arthrex ProStop Plus™ (Arthrex, Naples, FL) received marketing clearance in 2008 (K071456). The MBA® implant (now owned by Integra LifeSciences Corp., Plainsboro, NJ) received 510(k) marketing clearance in 1996 (K960692) because it was substantially equivalent to products on the market prior to device regulation. According to the FDA summary, the primary indication for the Subtalar MBA device is "as a spacer for stabilization of the subtalar joint. It is

designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.” (1) The MBAResorb Implant received 510(k) marketing clearance in 2005 (K051611). This implant employs the same basic mechanical features as the predicate MBA implant but is composed of a material (poly L-lactic acid) that is resorbed by the body. Predicate devices include the Osteomed Talar-Fit™ (K031155), Nexa Orthopedics Subtalar Peg (K032902 and K033046), Arthroereisis Implant Talus of Vilex (TOV, K041289), Instrateck (K080280), and Wright Medical Smith Sta-Peg (K792670).

#### *Related Protocol*

Total Ankle Replacement

#### **Policy (Formerly Corporate Medical Guideline)**

Subtalar arthroereisis is considered **investigational**.

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Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

#### **References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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16. Lee MS, Vanore JV, Thomas JL et al. Clinical Practice Guideline Adult Flatfoot Panel: American College of Foot and Ankle Surgeons (ACFAS). Diagnosis and treatment of adult flatfoot. *J Foot Ankle Surg* 2005; 44(2):78-113.